

REMARKS**Regarding the Amendments**

Amendment of the specification on page 1, first paragraph, updates continuing application information and as such does not constitute new matter.

The amendments to the specification on pages 1, 3, 8, 11, 15-19, 25-27, 33, 34, 39 and 42 (continuing on page 43) correct minor typographical errors. The amendments to the specification on page 38 correct typographical errors in reference citations. These amendments are not believed to constitute new matter.

The amendments to the specification on page 8, line 34 through page 9, line 9 and page 11, lines 10-20 specify the amino acids included in the designated hTNF- α fragments (see also page 4, line 27 through page 5, line 10; page 9, lines 12-13 and 17-18; page 11, lines 10-20 and 26-28; page 12, lines 10-20; page 15, lines 3-13; and page 34, lines 7 and 11). As described in the accompanying Declarations pursuant to 37 C.F.R. § 1.132 by Deborah A. Rathjen, the peptides synthesized on pages 30-33 of the specification were synthesized using the sequence information of mature hTNF- α . The sequence information of mature TNF- α is presented in Socher *et al.* (1985) *Proc. Natl. Sci. USA* 84:8829-8833, which is cited in the specification of U.S. Pat. Ser. No. 09/364,039 (now U.S. Pat. No. 6,416,757) at page 3, lines 23-24. (Rathjen Declaration 1/23/02, ¶¶ 3-5). The amino acid sequences added by amendment to the specification correspond to regions of the amino acid sequence of hTNF- α as reported in Socher *et al.* (Rathjen Declaration 1/23/02 ¶ 6), with the exception of residue 59 as mentioned in the caveat (Rathjen Declaration 1/23/02, ¶ 4 and Rathjen Declaration 5/19/01 ¶ 5). Therefore, no new matter has been added by the amendment. The Rathjen Declarations provided are copies of Declarations which were made of record in the great-great-grandparent application U.S. Pat. App. Ser. No. 09/364,039, now U.S. Pat. No. 6,416,757, and in the great-great-great-grandparent application U.S. Pat. App. Ser. No. 09/736,630, both identical specifications to the present application.

The amendments to the specification on page 32, lines 3-7, replace the typographical error of Thr-87 with Tyr-87. As described in the accompanying copy of the Declaration pursuant to 37 C.F.R. § 1.132 by John Young Yuen, peptides 309 and 323 were synthesized as described on pages 30-33 of the specification according to the sequences shown in Exhibits 1 and 2 of the attached Yuen Declaration using the sequence information of mature human TNF- α . The attached Yuen Declaration is a copy of that which was submitted on April 30, 2002 in connection with application U.S. Pat. App. Ser. No. 09/736,792, which is a continuation of the great-great-great-great-grandparent application of the present application and an identical specification, and in the great-great-great-great-grandparent application U.S. Pat. App. Ser. No. 09/736,630.

The sequence information for mature human TNF- α is presented in Socher *et al.* (1985) *Proc. Natl. Sci. USA* 84:8829-8833, which is cited in the specification of U.S. Pat. App. Ser. No. 09/364,039 at page 3, lines 23-24 (Rathjen Declaration 1/23/02, ¶¶ 3-5, copy submitted herewith), the great-great-great-great-grandparent of the present application and an identical specification. The amino acid sequences amended herein correspond to the peptide sequences synthesized as shown in Exhibits 1 and 2 and are in agreement with the regions of the amino acid sequence of mature hTNF- α as reported in Socher *et al.* (Rathjen Declaration 1/23/02 ¶ 6, copy submitted herewith, and John Young Yuen Declaration submitted herewith ¶¶ 4-6) which agree with other sequences known in the art for mature hTNF- α and are accepted by those of skill in the art as the sequence of mature human TNF- α . The Applicants submit that both the error in the sequences of peptides 309 and 323 and the correction of that error would have been obvious to one of skill in the art at the time the Application was filed given the publications cited in the attached Declarations, and those cited therein. A copy of the Declaration pursuant to 37 C.F.R. § 1.132 by Deborah A. Rathjen dated May 19, 2001, and incorporated by reference into the 1/23/02 Rathjen Declaration, is also submitted herewith. Both Rathjen Declarations were originally submitted to the Office in connection with U.S. Pat. App. Ser. No. 09/364,039 (now U.S. Pat. No. 6,416,757), the great-great-great-great-grandparent of the present application and an identical specification, and in the great-great-great-great-grandparent application U.S. Pat. App. Ser. No. 09/736,630. For the above reasons Applicants believe no new matter has been added by the amendment.

Regarding the Deposit of Biological Materials

Submitted herewith is a copy of the declaration pursuant to 37 C.F.R. § 1.132 of Stephen Kwik submitted in related applications U.S. Pat. App. Ser. Nos. 09/737,121 (now U.S. Pat. No. 6,448,380), 09/736,793 (now U. S. Pat. No. 6,498,237), and 09/736,792 (now U.S. Pat. No. 6,451,983) regarding the removal of restrictions on the deposits of biological material listed therein. The specification on page 5, line 26 through page 6, line 4; page 7, lines 11-20; page 9, lines 20-29; page 11, line 29 through page 12, line 2 and page 12, lines 26-35 has been amended to reflect the statements made in the § 1.132 declaration of Stephen Kwik. The above-identified applications are all identical specifications. The Applicant respectfully requests the Examiner to make the attached declaration of record in the present application. If additional documentation is needed, the Examiner is encouraged to telephone the undersigned at the number listed below.

Regarding the Sequence Listing Requirements

Applicants believe that the subject application is not one for which sequence data are required. Specifically, Applicants note that according to MPEP 2420 and 2421, compliance with 37 C.F.R. 1.821-1.825 is required only for applications containing nucleotide or amino acid sequence information filed on or after October 1, 1990.

The present application claims a priority date of August 7, 1990 (international filing date of PCT/AU90/00337, designating the U.S., published in English on February 21, 1991, which claims the benefit of Australian applications AU PJ5662, filed August 7, 1989, and AU PJ7576, filed November 24, 1989), and thus is not subject to the requirements of 37 C.F.R. 1.821-1.825. The priority claim is being made at the time of filing via the Application Data Sheet (co-filed herewith) and the specification amended to cross reference related applications in the instant Preliminary Amendment co-filed with the present continuation patent application.

The Applicants suggest that the subject application has fulfilled the requirements for examination. The Applicants earnestly request docketing of the subject application to the Examiner.

Application No.: Not Yet Assigned

18

Docket No.: 273402602309

Should the Examiner or Office of Initial Patent Examination have further questions they are urged to contact the undersigned.


CONCLUSION

If the Examiner believes a telephone conference would expedite prosecution of this application, a telephone call to either Gladys Monroy (Reg. No. 32,430) at (650) 813-5711 or the undersigned will be appreciated.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 273402602309. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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